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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/483,184 01/14/00 CRAIG

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EXAMINER

HM12/0703

Gray Cary Ware & Freidenrich LLP
Suite 1600
4365 Executive Drive
San Diego CA 92121-2189

CANELL A.K	
ART UNIT	PAPER NUMBER

1642

DATE MAILED:

07/03/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/483,184

Applicant(s)

Craig et al

Examiner

Karen Canella

Art Unit

1642



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 months MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____

2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-81 is/are pending in the application.

4a) Of the above, claim(s) 22-81 is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 1-21 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirements.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. _____

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

19) ☐ Notice of Informal Patent Application (PTO-152)

17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). nd 8/22

20) ☐ Other:

Art Unit: 1642

DETAILED ACTION

1. Acknowledgment is made of applicant's election with traverse of Group I, drawn to the polynucleotides constituting the Mcl-1 gene regulatory element, vectors and host cells thereof. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. Claims 1-81 are pending. Claims 22-81, drawn to non-elected inventions, are withdrawn from consideration. Claims 1-21 are examined on the merits.

Claim Rejections - 35 USC § 101

3. Claims 1-21 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific, substantial asserted utility or a well established utility. The asserted utility for the claimed polynucleotides of the Mcl-1 gene regulatory region is the providing of a means to modulate the apoptotic process in cells, thus allowing for the development of methods for intervening in pathological conditions associated with apoptosis (pg. 3, lines 9-13). It is known in the art that although the recombinant overexpression of the Mcl-1 protein can enhance the survival of hematopoietic cells and other cell types when placed under apoptosis -inducing conditions, both in vitro and in transgenic mice (Townsend et al, Oncogene 1998, Vol. 17, pp. 1223-1234, paper AF, of IDS filed 3/21/00 and Zhou et al, Blood, 1998, Vol. 92, pp. 3226-3239, paper no. AH of IDS filed 3/21/00), the use of the instant claimed gene regulatory region in the control of apoptosis has not been demonstrated by the specification. Yang et al (Journal of Cellular Physiology, 1996, Vol. 166, pp. 523-536, paper AJ, of IDS filed 3/21/00) teach that expression of Mcl-1 mRNA increased rapidly in human myeloblastic leukemia cells after exposure to inducers of monocyte/macrophage differentiation such as phorbol esters, or after exposure to certain chemotherapeutic agents such as colchicine and vinblastine. Townsend et al teach that

Art Unit: 1642

Mcl-1 expression is increased by chemotherapeutic agents which disrupt microtubule assembly by signaling through PKC which causes activation of ERK, ERK activation in turn, contributes to the increased Mcl-1 expression. However, it has been noted that increased expression of the Mcl-1 protein is associated with only a transient protection against apoptotic stimuli (Zhou et al, Blood, 1997, Vol. 89, pp. 630-643, paper AK, of IDS filed 3/21/00; Reynolds et al, Cancer Research, 1994, Vol. 54, pp. 6348-6352). Further, the specification does not teach how to affect changes of sufficient duration in the Mcl-1 protein level sufficient for the treatment of a disease state by utilization of the claimed Mcl-1 gene regulatory region. The specification provides no guidance on the use of the claimed Mcl-1 gene regulatory region, either for the prohibition of Mcl-1 protein expression to stimulate apoptotic cell death in cells associated with a cancerous condition, or for protecting populations of cells from apoptotic cell death, such as neurons. To treat cancer or protect neurons using the claimed Mcl-1 gene regulatory region would require further research to identify or reasonably confirm a "real-world" context of use. The specification essentially gives an invitation to experiment wherein the artisan is invited to elaborate a functional use for the disclosed Mcl-1 gene regulatory region. Because the claimed invention is not supported by a specific asserted utility for the reasons set forth, credibility of any utility cannot be assessed.

4. Claims 1-21 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific, substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Conclusion

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Canella whose telephone number is (703) 308-8362. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may be


Art Unit: 1642

left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Karen A. Canella, Ph.D.

Patent Examiner, Group 1642

July 1, 2001


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